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PROVIDER BULLETIN

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Coverage Decisions

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TO:

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Provider Bulletins/Updates are available on the Web at:
http://www.LNI.wa.gov/hsa/ProvBulletins/PbAmaAgree.htm

Topic — Page

Purpose

This Provider Bulletin describes:

- Coverage of bone morphogenetic protein for the treatment of long bone nonunions and for use during spinal fusion. This policy goes into effect on February 15, 2004 for State Fund and Self-Insurance claims in all locations.
- Noncoverage of IDET for discogenic back pain. This policy is currently in effect for State Fund and Self-Insurance claims in all locations.
- Noncoverage of kyphoplasty and vertebroplasty due to safety concerns about acrylic bone cement. This policy is currently in effect for State Fund and Self-Insurance claims in all locations.
- Noncoverage of thermal shrinkage for shoulder and anterior cruciate ligament injuries. This policy is currently in effect for State Fund and Self-Insurance claims in all locations.

Bone Morphogenetic Proteins (BMP)

What are Bone Morphogenetic Proteins?
Bone morphogenetic proteins (BMP) are proteins found in the human body that aid in bone modeling, repair, and development. Manufactured forms of BMP have been produced to induce bone formation by causing the differentiation of mesenchymal cells into chondroblasts and osteoblasts. To administer BMP locally, BMP is combined with an absorbable collagen sponge made from bovine Type I collagen.

What are Food and Drug Administration (FDA) indications for BMP?
The FDA has approved two manufacturers to market BMPs for two indications:

Company	Products	Protein Type	FDA Indications	Product Description
Stryker Biotech	OP-1 Implant	BMP-7	OP-1 acts as an alternative to autograft in recalcitrant long bone nonunion where use of autograft is not feasible and alternative treatments have failed.	OP-1 comes as a protein powder and is mixed with bovine bone collagen and sterile saline solution to form a paste. The paste is then placed between the broken ends of the bone during surgery.
Medtronic Sofamer Danek	InFUSE Bone Graft and LT-CAGE Lumbar Tapered Fusion Device system	InFUSE Bone Graft consists of BMP-2 and a bovine Type I collagen carrier.	The system is used during spinal fusions for patients with degenerative disc disease at one level from L4-S1. The device is implanted via anterior open or anterior laparoscopic approach.	InFUSE Bone Graft is combined with the LT-CAGE lumbar tapered fusion device. The cage is intended to maintain spacing within the spine while the InFUSE Bone Graft is intended to form bone for spine stabilization.

Is BMP a covered therapy for long bone nonunion?
The Insurer will cover Stryker Biotech's OP-1 Implant as an alternative to autograft in recalcitrant long-bone nonunions[1] where:

1) use of autograft is unfeasible [2]
   AND
2) alternative treatments [3] have failed.

When is OP-1 excluded from coverage?
The Insurer will not cover the OP-1 Implant for non-long bones fractures, fresh fractures, or spinal fusion**.**

Is BMP a covered therapy for use in spinal fusions?
The Insurer will cover Medtronic Sofamer Danek's InFUSE Bone Graft with BMP-2 and LT-CAGE Lumbar Tapered Fusion Device system for patients with degenerative disc disease[4] who have had at least 6 months of nonoperative treatment. InFUSE with the LT-CAGE is covered for:

1) single-level anterior lumbar spine fusion
   AND
2) implantation via anterior open or anterior laparoscopic approach
   AND
3) fusion at one level from L4-S1.

In addition, state fund claimants should meet the department's lumbar fusion guidelines, which may be found at www.Lni.wa.gov/omd/PdfDoc/MedTreat/2002MTG31to39.pdf.

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[1] Fracture nonunion must be documented by a minimum of two sets of radiographs separated by at least 90 days. Each set should include multiple views of the fracture site. The baseline radiograph is the one done at the time of injury or, if surgery took place, then from the date of surgery. A physician must include a written interpretation stating that no clinically significant evidence of fracture healing occurred between the two sets of radiographs.

[2] Autograft use may be deemed unfeasible because the patient:

- Had a previous autograft, and tissue is no longer available;
- Does not have sufficient autogenous tissue for the intended purpose;
- Is advanced in age (> 65 years) or obese;
- Shows morbidity (pain, infection, or fracture) at autograft donor site;
- Has excessive risk of anatomic disruption (including fracture) from harvesting autograft from donor site;
- Has poor bone quality (osteoporosis)
- Has concurrent medical conditions and comorbidities that increase the risk of autograft.

[3] Alternative treatments may include the following:

- Cast immobilization or other nonoperative approaches
- Fixation (internal and external)
- Revision of fixation
- Autograft
- Allograft
- Compression
- Dynamization
- Electrical or ultrasound bone growth stimulation

[4] Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history, function deficit, and/or neurological deficit and radiographic studies. The degenerative disc disease patients may also have up to Grade I spondylolisthesis at the involved level.

When is the InFUSE Bone Graft and LT-CAGE system excluded from coverage?
The Insurer will not cover InFUSE Bone Graft and LT-CAGE system for ANY of the following indications:

1) multiple level lumbar fusions
2) fusions of the thoracic or cervical spine
3) augmentation of bone autografting.

The Insurer will not cover the InFUSE Bone Graft and LT-CAGE system for patients with allergies to titanium or titanium alloys. InFUSE is not covered for bone fracture nonunion.

What additional contraindications to BMP result in exclusion from coverage?
Neither the OP-1 Implant nor the InFUSE Bone Graft and LT-CAGE system is covered for patients with ANY of the following contraindications:

1) hypersensitivity to BMP or to bovine collagen
2) skeletally immature (< 18 years of age or no radiographic evidence of epiphyses closure)
3) pregnant or nursing
4) history of malignancy
5) resected tumors at or near the implant site
6) hepatic or renal impairment
7) autoimmune disease or suppressed immune system.

Neither product is covered for non-FDA indications, such as restorative dental surgery or craniofacial surgery.

Are multiple BMP treatments covered?
Due to concerns about immune response, the Insurer will cover BMP once per patient. For example, the Insurer will not cover InFUSE for a patient who previously received OP-1.

What information should patients know prior to receiving BMP?
Physicians should inform their patients that BMP is a recombinant human protein and that the collagen carrier is derived from bovine Type I collagen.

Does BMP require prior authorization?
State fund and Self-Insured claimants undergoing in-patient surgery for fractures or spinal fusions must receive prior authorization. For State Fund claims, physicians should request authorization from the state's utilization review vendor, Qualis Health. Qualis will make a recommendation to the Claim Manager, who will make the final determination.

What are the billing codes for BMP?
Neither OP-1 nor InFUSE has unique billing codes at this time. If Claim Managers determine that the surgery is appropriate for reimbursement, they will authorize the standard codes for the requested surgery.

Intradiscal Electrothermal Therapy (IDET)

What is intradiscal electrothermal therapy (IDET)?
Intradiscal Electrothermal Therapy (IDET) is a procedure that involves inserting a hollow needle into a painful vertebral disc. An electrothermal catheter is passed through the needle into the disc and around the outer edge of the central nucleus. Then, the wire is heated over approximately 15 minutes to a temperature of 90 degrees Celsius.

IDET is intended to address discogenic pain. Advocates of IDET have postulated several explanations for its mechanism of action. These include thermal destruction of nociceptors, stabilization of the disc secondary to collagen shrinkage in the annulus, and destruction within the disc of chemical mediators of pain. However, experimental investigations have not validated the correctness of the postulated mechanisms of action.

Is IDET a covered therapy?
At this time, IDET remains a noncovered therapy because it is considered controversial and investigational.

Several studies have been conducted to examine the efficacy of IDET. The majority of data comes from small case series studies that lack comparison groups. Without comparison groups, it is not possible to establish a causal relationship between a treatment and an outcome. Therefore, these studies have not demonstrated the efficacy of IDET in the treatment of back pain.

One randomized controlled trial was recently published with results suggesting that IDET is marginally effective in improving pain and function. However, presentations of a second randomized controlled trial reported that IDET was no more effective than placebo in the treatment of discogenic pain. Due to the differing results in the high quality studies, IDET is considered controversial and is not a covered procedure.

The Department will reconsider its decision if presented with peer-reviewed medical literature demonstrating the therapy's safety and effectiveness.

Bone Cements for Use during Kyphoplasty and Vertebroplasty

What are kyphoplasty and vertebroplasty?
Kyphoplasty and vertebroplasty are surgical procedures used to treat compression fractures of the spine. Both procedures use polymethylmethacrylate bone cement to stabilize the fractured bone.

Are kyphoplasty and vertebroplasty covered procedures?
Kyphoplasty and vertebroplasty for the treatment of spinal compression fractures remain noncovered therapies.

The Food and Drug Administration has issued a notification expressing concern over the safety of polymethylmethacrylate (acrylic) bone cements used during the procedures. Complications associated with acrylic bone cement include soft tissue damage, nerve root pain and compression, pulmonary embolism, respiratory and cardiac failure, abdominal intrusions, and death.

For more information, please see http://www.fda.gov/cdrh/safety/bonecement.html.

Thermal Shrinkage for Instability

What is thermal shrinkage?
Thermal shrinkage procedures use thermal probes to apply heat to lax tissue within a joint. The procedure shrinks the collagen fibers and is intended to reduce joint laxity in order to increase joint stability.

Is thermal shrinkage a covered therapy?
At this time, thermal shrinkage is not a covered therapy for any indication, including:

1) shoulder instability
2) anterior cruciate ligament (ACL) laxity

Published literature has not substantially established the safety or effectiveness of either thermal capsulorrhaphy or thermal shrinkage of the ACL. Therefore, the procedures are considered investigational.

The Department will reconsider its decision if presented with peer-reviewed medical literature demonstrating the therapy's safety and effectiveness.

Where is more information available?

Contact Grace Wang at wann235@LNI.wa.gov or (360) 902-5227 for more information about technology assessments. Full assessments are available online at http://www.LNI.wa.gov/omd/MedCov.htm.

For more information about the department's utilization review contractor, Qualis Health, see Provider Bulletin 02-04. The Bulletin may be downloaded from http://www.LNI.wa.gov/hsa/ProvBulletins/PbFiles/PB_02-04.pdf.

For additional information about fees, see the Medical Aid Rules and Fee Schedules. The information may be found online at www.LNI.wa.gov/hsa.